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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,506	05/06/2004	Rafail Zubok	SPINE 3.0-455	2911
530 7590 04/08/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 04/08/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,506

Applicant(s)

ZUBOK ET AL.

Examiner

JERRY CUMBERLEDGE

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S5108)
- Paper No(s)/Mail Date 10/31/2007.
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9-13, 20 and 21 rejected under 35 U.S.C. 102(b) as being anticipated by Slotman et al. (US Pat. 5,599,279).

Slotman discloses a system for insertion of a cervical disc replacement device handle, comprising: an insertion handle (Fig. 7) comprising a shaft (Fig. 7, ref. 214) having a proximal end a distal end (Fig. 7), a longitudinal bore extending from the proximal end toward the distal end (Fig. 10, ref. 224)(column 5, lines 20-54), and an actuator (Fig. 7, ref. 212)(column 14-17) disposed substantially at the proximal end of the shaft (Fig. 7) and an engagement member (Fig. 7, ref. 218) disposed at the distal end of the shaft, an insertion plate (Fig. 7, ref. 220) that maintains first and second members of an intervertebral disc replacement device in registration with one another for substantially simultaneous insertion into an intervertebral disc space of a spinal column (Fig. 7), the insertion plate operable for detachable engagement with the insertion handle (Fig. 8)(column 5, lines 29-41); and a pushing member (Fig. 10, ref. 234) having a proximal end and a distal end and being slideably receivable within the longitudinal bore (Fig. 10). The shaft is operable to permit the first and second members of the intervertebral disc replacement device to be at least one of inserted into and

moved within the intervertebral disc space without substantially changing their orientation with respect to one another (Fig. 7). The insertion handle is detachable from the insertion plate to facilitate removal of the insertion handle when the intervertebral disc replacement device is positioned within the intervertebral disc space (Fig. 8)(column 5, lines 29-41). The insertion plate includes a base (Fig. 7), having a posteriorly directed surface (Fig. 7, interior surface of ref. 220) directed toward the first and second members of the intervertebral disc replacement device (Fig. 7), a spaced apart anteriorly directed surface (Fig. 7, exterior surface of ref. 220), and an insertion member (Fig. 7, projection of ref. 220, near distal end) extending away from the anteriorly directed surface of the base (Fig. 7); and one of the insertion member of the base and the engagement member of the shaft includes a stem (Fig. 7, portion projecting from ref. 220), and the other of the insertion member of the base and the engagement member of the shaft includes a bore (Fig. 8 and Fig. 9, bore through which ref. 220 can slide) such that the stem is receivable in the bore and the insertion handle and the insertion plate detachably engage one another (Fig. 8)(Fig. 9). At least one of: the stem and the bore are sized and shaped for achieving frictional engagement; and at least one of the stem and the bore include tapered surfaces to achieve the frictional engagement (Fig. 7). The actuator is operable to cause the shaft and the insertion plate to disengage from one another (Fig. 7)(column 5, lines 29-41). Actuation of the proximal end of the pushing member causes the distal end thereof to engage the insertion plate and separate the shaft from the insertion plate (Fig. 7)(column 5, lines 29-41). The proximal end of the shaft includes at least one first flange (Fig. 10, flanges of ref. 228,

bottom) and the proximal end of the pushing member includes at least one second flange (Fig. 10, flanges of ref. 22, top); and respective forces applied to the first and second flanges facilitates slideable actuation of the pushing member within the longitudinal bore and engagement of the distal end of the pushing member with the stem of the insertion plate to separate the insertion handle from the insertion plate (Fig. 10). The urging of the first and second flanges towards one another results in the respective forces to cause the insertion handle and the insertion plate to separate from one another (Fig 10).

A system for insertion of a cervical disc replacement device, comprising: an insertion handle (Fig. 7) having a shaft (Fig. 7, ref. 214) having a proximal end (Fig. 7), a distal end (Fig. 7), and a longitudinal bore extending from the proximal end toward the distal end (Fig. 10, ref. 224)(column 5, lines 20-54), and an engagement member (Fig. 7, ref. 218) disposed at the distal end of the shaft (Fig. 7); and an insertion plate (Fig. 7, ref. 220) having a base (Fig. 7) having a posteriorly directed surface (Fig. 7, interior surface of ref. 220) directed toward the first and second members of the intervertebral disc replacement device (Fig. 7), a spaced apart anteriorly directed surface (Fig. 7, exterior surface of ref. 220), and an insertion member (Fig. 7, ref. projection of ref. 220) extending away from the anteriorly directed surface of the base (Fig. 7), the insertion plate capable of maintaining first and second members of an intervertebral disc replacement device in registration with one another for substantially simultaneous insertion into an intervertebral disc space of a spinal column (Fig. 7), the insertion plate operable for detachable engagement with the insertion handle Fig. 8)(column 5, lines

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29-41).

A system for insertion of a cervical disc replacement device, comprising:
an insertion handle (Fig. 7) comprising a shaft (Fig. 7, ref. 214) having a proximal end (Fig. 7), a distal end (Fig. 7), a longitudinal bore extending from the proximal end toward the distal end (Fig. 10, ref. 224)(column 5, lines 20-54), and an actuator (Fig. 7, ref. 212)(column 14-17) disposed substantially at the proximal end of the shaft and an engagement member disposed at the distal end of the shaft (Fig. 7); an insertion plate (Fig. 7, ref. 220) having a base (Fig. 7) having a posteriorly directed surface (Fig. 7, interior surface of ref. 220) directed toward the first and second members of the intervertebral disc replacement device (Fig. 7), a spaced apart anteriorly directed surface (Fig. 7, exterior surface of ref. 220), and an insertion member extending away from the anteriorly directed surface of the base, the insertion plate capable of maintaining first and second members of an intervertebral disc replacement device in registration with one another for substantially simultaneous insertion into an intervertebral disc space of a spinal column, the insertion plate operable for detachable engagement with the insertion handle; and a pushing member having a proximal end and a distal end and being slideably receivable within the longitudinal bore.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slotman et al. (US Pat. 5,599,279) in view of Wagner et al. (US Pat. 5,683,464).

Slotman et al. disclose the claimed invention except for the insertion handle comprises an anti-rotational mechanism disposed at least one of the distal end of the shaft and the stem, the antirotational mechanism resisting rotation of the stem within the bore and thereby assisting maintenance of the relative positions of the insertion handle and the intervertebral disc replacement device when they are engaged. The anti-rotational mechanism includes at least one key element disposed on one of the stem and the bore, and at least one slot element disposed on the other of the stem and the bore, the at least one key element and the at least one slot element engaging one another when the stem is disposed in the bore in order to resist rotation of the stem within the bore. The bore is disposed longitudinally within, and terminates at, the distal end of the shaft; and at least two key elements are disposed at the distal end of the shaft and communicate with the bore such that a diameter of the bore terminating at the distal end of the shaft elastically increases as the stem is urged into the bore to facilitate frictional engagement between the stem and the shaft.

Wagner et al. disclose an insertion handle (Fig. 14) with a stem (Fig. 14, ref. 112) and a bore (Fig. 14, ref. 118). The stem includes an anti-rotational mechanism (Fig. 10, the shape of the stem, which locks the components together). The antilock mechanism comprises key elements (Fig. 14, left and right flanges of ref. 112) that fit into a bore (Fig. 14, ref. 118). There is an elastic engagement between the stem and the bore,

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since the components can be made of plastic (column 8, lines 41-51). This arrangement allows the handle and the stem to be firmly yet releasably locked together (column 8, lines 66-67 and column 9, line 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Slotman et al. with the stem and bore. The stem includes an anti-rotational mechanism. The antilock mechanism comprises key elements that fit into a bore. There is an elastic engagement between the stem and the bore, since the components can be made of plastic, all as taught by Wagner et al. This arrangement allows the handle and the stem to be firmly yet releasably locked together (column 8, lines 66-67 and column 9, line 1).

Response to Arguments

Applicant's arguments filed 12/17/2007 have been fully considered but they are not persuasive.

With regard to Applicant's arguments that the Slotman et al. reference does not disclose an insertion plate and a pusher member with ends within a bore, the examiner respectfully disagrees. The Slotman reference discloses an insertion plate (Fig. 7, ref. 220) and a pushing member (Fig. 10, ref. 234) having with ends within a bore (Fig. 10).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733